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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,488	09/16/2003	Joseph P. Errico	SPINE 3.0-437 P P P P P P I C	2425
530 7590 12/24/2009 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 12/24/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/663,488	Applicant(s) ERRICO ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,11-13,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 and 15 is/are allowed.
- 6) ☒ Claim(s) 1,5,6,11,12 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/24/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/09 has been entered.

Prosecution on the merits of this application is reopened on claims 1,5,6,11,12,16 considered unpatentable for the reasons indicated below:
A newly discovered reference to Steffee (5443514) in view of Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 9/24/09 prompted the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,5,6,11,12,16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffee (5443514) in view of Jackson (6821298) and Winterbottom et al. (2003/83747). Steffee disclose (Fig. 12) an intervertebral spacer device having first and second baseplates **10** with each baseplate having an inwardly facing surface **22** and an outwardly facing surface **20**. Steffee also discloses (Fig. 2) that the inwardly facing surfaces of the baseplates include a perimetrical region **60** which includes a plurality of engagement holes **58** disposed within the perimetrical region and the holes having first and second ends. It can be seen that the first end faces toward the perimetrical region of one of said first and second baseplates and the second end disposed within the other of said perimetrical region of the other one of said first and second baseplates.

However, Steffee fails to disclose mounting the baseplates to one another. Jackson teaches (Figs. 1,33,34) that spinal implants can be mounted or linked to one another. It would have been obvious to one of ordinary skill in the art to use a link **12** as taught by Jackson with the spinal plates of Steffee such that they are retained in their position and cannot shift towards or apart from one another.

Steffee further discloses (Fig. 4) a manipulation tool **80** having a proximal end **96**, a distal end **104**, and a shaft **118** located along a longitudinal axis of the manipulation tool between the two ends. The longitudinal axis of said shaft being perpendicular to a longitudinal axis of said engagement holes.

However, Steffee does not disclose the shaft including a central channel coaxial with the longitudinal axis of the tool and houses a post that is disposed entirely within said distal end of said manipulation tool for a first position and a second position corresponding to the post extending outwardly from said distal end of the manipulation tool to be disposed within any of the plurality of said engagement holes of a plate. Winterbottom et al. teach (Figs. 21,22) a manipulation tool **184** with a shaft **208** that defines a channel between the end arms **218,220** see Figs. 24,25. Winterbottom also teaches that the shaft can be disposed entirely within the manipulation tool, paragraph 175. Winterbottom further teaches (Fig. 73) that disposed within the shaft ends are posts 520,522 when in the second position of extended out from the tool, are disposed within holes and also would be entirely within the tool when the shaft is drawn in the tool for the first position. It would have been obvious to one of ordinary skill in the art to use a manipulation tool with posts as taught by Winterbottom et al. for the tool of Steffee as modified with Jackson such that the plates are positively engaged via the posts when inserting them and cannot slip from the tool.

Regarding claims 5,6,11, the plates are capable of being implanted in an anterior approach or antero-lateral approach. With respect to claim 12, the plates have holes that extend parallel to a medial-lateral dimension and because it has a depth since the hole is 3-dimensional it can be said to be parallel to an anterior-posterior plane. Regarding claim 16, it can be interpreted that Steffee discloses at least two holes in the perimetrical region, but does not explicitly teach that there are three engagement holes in the perimetrical region. It would have been obvious to one of ordinary skill in the art at

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the time the invention was made to use three engagement holes since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, depending on the patient, if larger size plates are needed because the individual possesses large vertebral dimensions, it would be common sense to incorporate more holes or add a third hole to the plates such that it provides more holes for engagement as it is an obvious expedient.

Allowable Subject Matter

Claims 13,15 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738